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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,408	04/25/2006	Francesco Cilurzo	207,565	1408

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EXAMINER	
SUTTON, DARRYL C	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,408	CILURZO ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-26* is/are pending in the application.

4a) Of the above claim(s) *6-11,18-20,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-14,16,17 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 08/09/2010. No new claims have been added. Claims 15 and 27 have been canceled.

Applicant's arguments filed 08/09/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 12-14, 16, 17 and 21-24 are ejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the limitations "consisting essentially of between 40% and 80% by weight of a filmogenic substance consisting of maltodextrin" and "wherein the films are free from hydrocolloids." Maltodextrin is known in the art as a hydrocolloid, see

Chen et al., US 2003/0068378, paragraph [0059]. Accordingly, the combination of the limitations in the instant claims is confusing.

Claim 16 recites the limitation "other excipients" in line 2 of the claim. Claim 16 is dependent on claim 1 however claim 1 does not contain the limitation "excipient" therefore the term "other" excipient in claim 16 is confusing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Note: Although instant claim 1 is limited to films "consisting essentially" of maltodextrin, a plasticizer and an active ingredient, instant claim 16 is limited to excipients that can be added to the film of claim 1. The Examiner has interpreted this to mean that the excipients of claim 16 are not essential to the film and therefore do not change or materially affect the basic and novel properties, i.e. the disintegration times, of the film of instant claim 1, see MPEP 2163. Accordingly, prior art that discloses the essential components of instant claim 1 along with any of the components of instant

claim 16 will still read on the limitation "consisting essentially of maltodextrin, a plasticizer and an active agent" of instant
claim 1.

(1) Claims 1, 4, 5, 12, 13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. (US 2004/0096559) in view of Chen et al. (US 2003/0068378).

Barkalow et al. teach edible thin films and methods of making and using same (Abstract, [0001]). The edible film product consist of a film former such as starch hydrolyzed products including maltodextrin in amounts from 5% to about 60%; the film comprises a plasticizer such as polyethylene glycol, propylene glycol, sorbitol and glycerin and other polyols in amounts of from 0 to 20% [0024], [0026], [0042], [0087] and [0089]. The product includes medicaments such as pharmaceutical agents [0027], [0091] and [0092]. Any food grade filler can be used to produce the film, such as microcrystalline cellulose and talc, in amounts of approximately 1% to 30% [0088]. One process for forming the edible films includes (1) an aqueous solution is formed by blending film-forming materials together with water and agitated until the powdered materials are mostly hydrated and few lumps are present; (2) to this mixture, plasticizers, softening agent, colors, sweeteners, cooling agents, and active ingredients are blended together to form a homogenous solution; and (3) this solution is then applied onto a suitable carrier, and then dried [0062]. The carrier material should be impermeable to the film coating, allowing the film coating to disperse evenly onto the

carrier. This also allows for ease of removal of the film from the carrier [0063]. The casting or applying of the solution onto a suitable carrier material can be performed using any conventional coating technique such as knife over plate, roll over roll, reverse roll and various extrusion techniques [0065]. The edible thin films can be designed to be dispensed or accessed form the container in individual servings [0071]. It should be appreciated that any suitable type, number and arrangement of process procedures or steps, e.g. mixing, heating, drying, cooling, addition of ingredients, process parameters, e.g. temperature, pressure, pH, process times, or the like can be utilized to practice the present invention [0102].

Barkalow et al. do not teach a specific embodiment comprised of 40-80% maltodextrin, 15-55% of a plasticizer and 0.05-30% of an active agent.

Chen et al. teaches a mucosal surface coating forming film containing a water soluble hydrocolloid which includes an effective dose of an active agent (Abstract, [0011]). In an embodiment of the invention, the hydrocolloid includes a polymer consisting of a natural polymer such as a polysaccharide; in addition, the film further includes a plasticizer; and may further include an active agent such as a therapeutic agent or a dietary supplement [0012] and [0014]. Plasticizers include glycerin, sorbitol, propylene glycol, polyethylene glycol, triethyl citrate, acetyl triethyl citrate and other citrate esters [0041]. Active agents include analgesics, anti-Parkinson's medication, antihistamines, anti-hypertensives, anti-inflammatories, antimigraines, antiemetics, antipsychotics, anti-asthmatics and nutritional supplements [0042]. A factor that plays a significant role in determining the properties of the composition is the viscosity of the

hydrocolloid [0057]. The hydrocolloid is provided in a range of 5-99% [0058]. In particular embodiments a water-soluble non-gelling natural polysaccharide or derivatives such as maltodextrins or colloidal silicon dioxide can be used [0059] and [0060]. The percentage of ingredients incorporated into the film include a plasticizer at 0.5 to 20% and active agents from 0.01-75% [0061]. The films can be casted onto siliconized polyester or extruded to desired thickness [0063] - [0065]. Preparation of the films can include mixing at 70°C [0085].

Chen et al. do not teach a specific embodiment comprised of 40-80% maltodextrin, 15-55% of a plasticizer and 0.05-30% of an active agent.

At the time of the invention, it would have been obvious to modify the composition of Barkalow et al. to be comprised of the pharmaceutical agents, such as antiemetics, of Chen et al. in amounts of 0.01% to 75% since they are taught to be deliverable from edible films comprised of substantially the same components in those amounts.

Barkalow et al. and Chen et al. do not teach the specific ranges of maltodextrin, plasticizer and active agent. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Barkalow et al. teaches from 5% to about 60% maltodextrin versus between 40 and 80%; from 0% to 20% of plasticizers versus 15% to 55%; and Chen et al. teaches 0.01% to 75% of active agent versus 0.05% to 30% of instant claim 1.

(2) Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. and Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Zyck et al. (US 2003/0054039).

Barkalow et al. and Chen et al. are discussed *supra*.

Barkalow et al. and Chen et al. do not teach the DE value of maltodextrin.

Zyck et al. teach edible films comprised of film forming agents such as maltodextrin with a DE of less than 20. Medicaments and other additive agents can be incorporated into the edible films (Abstract, [0010]).

Zyck et al. do not teach a specific embodiment of a film consisting of essentially maltodextrin, a plasticizer and active ingredient.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use the maltodextrin of Zyck et al. as the maltodextrin source in the films suggested by combining Barkalow et al. and Chen et al.

Zyck et al. do not teach the specific range of DE of the maltodextrin. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Zyck et al. teaches maltodextrin of DE less than 20 versus less than 50 and between 11 and 40 of instant claims 2 and 3.

(3) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. and Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Falkenhausen et al. (WO 2002/02085), US 2004/0028732 provided as a translation guide.

Barkalow et al. and Chen et al. are discussed *supra*.

Barkalow et al. and Chen et al. does not teach the antiemetic compound ondansetron.

Falkenhausen et al. teach a rapidly disintegratable dosage form which is sheet-like and comprised of a matrix which comprises a water soluble polymer and at least one active ingredient (Abstract, [0001]). To improve the esthetic properties and in order to reduce the fragility or brittleness, glycerol or propylene glycol may be used [0030]. Suitable active ingredients are therapeutically active compounds such as ondansetron, in amounts of up to 50 mg [0019]. It is possible to produce the dosage forms starting with a polymer melt of the matrix polymer [0037], i.e. the polymer, solvent, and active are combined then heated. The melt is spread onto a suitable substrate and left there to cool. Processing though the polymer melt is unsuitable if the intended active ingredient is instable or volatile at the melting point of the polymer melt [0038].

Falkenhausen et al. does not teach a specific embodiment of a film comprised of maltodextrin, a plasticizer and ondansetron.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP

2144.07. Accordingly, it would have been obvious to use the ondansetron of Falkenhausen et al. as the antiemetic active agent in the film suggested by combining Barkalow et al. and Chen et al.

(4) Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al., Chen et al. and Falkenhausen et al. as applied to claim 14 above, and further in view of Kasper et al. (US 4,222,973).

Barkalow et al., Chen et al. and Falkenhausen et al. are discussed *supra*.

Barkalow et al., Chen et al. and Falkenhausen et al. do not teach the specific method steps of instant claims 21-24.

Kasper et al. teach that release papers have long been used for casting films. Conventionally, the papers have been coated with silicon which provides a release layer between the cast surface and the paper, allowing it to be easily removed from the paper (column 1, lines 15-24).

Kasper et al. do not teach a film comprised of maltodextrin.

At the time of the invention, it would have been obvious to modify the methods of Barkalow et al. to include the method step of heating the maltodextrin, plasticizer, active ingredient and solvent since Barkalow et al. teaches that the components are mixed and that any suitable type, number and arrangement of process procedures or steps, e.g. mixing, heating, drying, cooling, addition of ingredients, process parameters, e.g. temperature, pressure, pH, process times, or the like can be utilized. Heating the mixture would reasonably be expected to assist in the solubilization of the components

added to the water. Falkenhausen et al. teaches a polymer melt method comprised of similar method steps and including heating the solution; and that it is not preferably to process the composition at heats which cause instability of the active. Accordingly, the efficacy of the active is optimized through routine experimentation by varying the temperature at which the solution is heated to maximize the formation of a homogenous solution while preventing degradation of the active due to heat.

At the time of the invention, it would have been obvious to use the silicone paper of Kasper et al. as the carrier in the method suggested by combining Barkalow et al. and Chen et al. and Falkenhausen et al. motivated by the desire to be able to easily remove the film for use or further processing as taught by Kasper et al., and since Barkalow et al. require carriers that allow for ease of removal of the film from the carrier as discussed *supra*.

(5) Claims 1, 4, 5, 12, 13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0068378).

Chen et al. is discussed *supra*.

Chen et al. do not teach a specific embodiment comprised of 40-80% maltodextrin, 15-55% of a plasticizer and 0.05-30% of an active agent.

The specific combination of features claimed is disclosed within the broad generic genera/ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference

does not provide specific motivation to select this specific combination of variables: film polymers, optional ingredients and active ingredients, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742. Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients maltodextrin, plasticizer, i.e. polyethylene glycol or propylene glycol, and active agent, i.e. an antiemetic, to arrive compositions "yielding no more than one would expect from such an arrangement".

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third

composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly, it would have been obvious to combine maltodextrin and colloidal silicon dioxide since as discussed *supra* Chen et al. teach their equivalence.

Chen et al. does not teach the specific ranges of maltodextrin, plasticizer and active agent. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Chen et al. teaches from 5-99% maltodextrin versus between 40 and 80%; from 0.5% to 20% of plasticizers versus 15% to 55%; and 0.01% to 75% of active agent versus 0.05% to 30% of instant claim 1.

(6) Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Zyck et al. (US 2003/0054039).

Chen et al. is discussed *supra*.

Chen et al. do not teach the DE value of maltodextrin.

Zyck et al. is discussed *supra*.

Zyck et al. do not teach a specific embodiment of a film consisting of essentially maltodextrin, a plasticizer and active ingredient.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP

2144.07. Accordingly, it would have been obvious to use the maltodextrin of Zyck et al. as the maltodextrin source in the films of Chen et al.

Zyck et al. do not teach the specific range of DE of the maltodextrin The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Zyck et al. teaches maltodextrin of DE less than 20 versus less than 50 and between 11 and 40 of instant claims 2 and 3.

(7) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Falkenhausen et al. (WO 2002/02085), US 2004/0028732 provided as a translation guide.

Chen et al. is discussed *supra*.

Chen et al. does not teach the antiemetic compound ondansetron.

Falkenhausen et al. is discussed *supra*.

Falkenhausen et al. does not teach a specific embodiment of a film comprised of maltodextrin, a plasticizer and ondansetron.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use the ondansetron of Falkenhausen et al. as the antiemetic active agent in the film of Chen et al.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612